Roberts, H. W., Wagh, V. K., Sullivan, D. L., Hidzheva, P., Detesan, D. I., Heemraz, B. S., Sparrow, J. M., & O'Brart, D. P. S. (2019). A randomized controlled trial comparing femtosecond laser–assisted cataract surgery versus conventional phacoemulsification surgery. *Journal of Cataract and Refractive Surgery*, *45*(1), 11-20. https://doi.org/10.1016/j.jcrs.2018.08.033

A randomised controlled trial comparing femtosecond laser assisted cataract surgery vs. conventional phacoemulsification surgery

Short title: FLACS vs CPS trial

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Key Words: cataract, phacoemulsification, femtosecond laser assisted cataract surgery, cataract surgery

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Financial Support: Alcon Inc, Forth Worth, TX, USA. Grant number: IIT #17440075. The funding organisation had no role in the design or conduct of this research.

Financial disclosure: Professor O'Brart has undertaken paid consultancy work for Sooft Italia SPA and Alcon Inc in the past 12 months. No conflicting relationship exists for any other author.

This work has not previously been presented or published.

Abstract

Purpose

To compare the clinical results of conventional phacoemulsification surgery (CPS) to femtosecond laser (FL) assisted cataract surgery (FLACS).

Setting

Guy's & St Thomas' NHS Foundation Trust, London, UK

Design

Single-centre prospective randomised interventional case-controlled trial

Methods

400 eyes of 400 patients undergoing cataract surgery were randomised to receive either CPS or FLACS. FLACS was performed with a LenSx (Alcon Inc) and all operations were performed with an Infiniti machine (Alcon Inc). Visual acuity (VA), refraction, central corneal thickness (CCT) central foveal thickness (CFT), endothelial cell loss (ECL), and rates of intraoperative and postoperative complications were recorded. Quality of life outcomes were measured with EuroQOL's EQ-5D and patient reported quality of vision with Cat-PROM5.

Results

400 eyes of 400 patients were randomised to receive CPS (n=200) or FLACS (n=200). 3.5% of FLACS patients were not able to complete FL treatment and received CPS. Unaided VA (LogMAR) after CPS was 0.15±0.21 and 0.15±0.19 after FLACS (p=1), and pinhole corrected VA was 0.04±0.12 and 0.04±0.12 respectively (p=1). Increase in CCT was 13μm±19 after CPS and 15μm±25 after FLACS(p=0.5). ECC loss was -9.7%±13.7 after CPS and -10.2%±13.7 after FLACS(p=0.76). Refractive mean spherical equivalent error was -0.14±0.60 dioptres (D) after CPS and -0.12±0.60D for

FLACS(p=0.74). Change in CFT was 9μm±35 after CPS and 6μm±35 after FLACS(p=0.55). Rate of posterior capsular rupture (PCR) was 3% and 0% respectively(p=0.03).

Conclusions

This study confirms, in the majority, the non-significant differences between these two treatment modalities notwithstanding a significant reduction in PCRs in the FLACS group.

Word count of abstract: 248 words

Introduction

The introduction of femto-second laser (FL) technology to allow the automation of a number of surgical steps within cataract extraction has been claimed to offer potential advantages of reduced complications and better visual outcomes through greater surgical precision and reproducibility[1,2]. However, systems to undertake FL assisted cataract surgery (FLACS) are expensive both to purchase and use. In a previous study we estimated FLACS adds £167 (approx. 220USD) to each operation within the context of a state-funded healthcare system[3]. From a public health perspective, costs may be mitigated by improved safety leading to increased reliability and reduced post-operative need for additional clinical or surgical interventions, and better patient outcomes[4].

A meta-analysis of FLACS vs CPS performed by Chen et al, identified 9 randomised controlled trials (RCTs)[1,2,5-13]. Overall, they found that FLACS significantly reduced effective phacoemulsification time (EPT) compared to CPS. This did not translate into a difference in central corneal thickness or endothelial cell count at one week or beyond. The rates of surgical complications were similar. The post-operative corrected visual acuity was statistically superior in FLACS at 1 week and 6 months post-operatively but not at 1-3 months. There was no statistically significant difference in uncorrected visual acuity at any time point.

Fortunately for all stakeholders, the rates of complications of cataract surgery are low. Therefore, large studies are required to be adequately powered to investigate differences in safety. The largest RCT to investigate complication rates with FLACS

compared to CPS published to date included 200 eyes and reported one anterior capsular tear in the FLACS group and no events of posterior capsular rupture (PCR) in either group[14]. With such low rates of complications, such studies are often underpowered to detect differences in safety. The largest case control study included over 7000 cataract operations (3371 FLACS and 3784 CPS) and found increased risk of vitreous loss in the CPS group (1.4% vs 0.8%)[15].

A recent Cochrane Review of 16 RCTs including 1638 eyes concluded, 'There is currently not enough evidence to determine the benefits and harms of laser-assisted cataract surgery compared with standard ultrasound cataract surgery. The evidence is uncertain because current studies have not been large enough to provide a reliable answer to this question'[16].

Our aim was to complete the largest RCT published to date comparing FLACS with CPS with the intention to inform clinical practice and health policy worldwide. As there have been a lack of patient reported outcome measures (PROMs) in previous RCTs, this study aimed to correct this by measuring quality of life with EuroQOL's EQ-5D and patient reported quality of vision with Cat-PROM5[17,18].

Methods

The study design was a prospective randomised interventional case-controlled study at a single University Hospital (Guy's & St Thomas' Hospital NHS Foundation Trust, London, UK) to compare FLACS with CPS (Clinicaltrials.gov registration number NCT02825693). The study was approved by local Research & Development and Cambridge South Research Ethics Committee (reference 16/EE/0180). This study was conducted adhering to the tenets of the Declaration of Helsinki.

Patients were screened, recruited and informed consent obtained from routine cataract clinics by members of the trial team (HWR, VKW) as per the trial protocol (Version 2.0, 18/05/2016). Inclusion and exclusion criteria are listed in **Error! Reference source not found.**. Within the enrolment visit, patients had a complete ophthalmological examination. Only one eye per patient was enrolled to the study. Patients were randomised to receive CPS or FLACS in equal proportions using computer generated random number tables (Microsoft Excel, Microsoft Corp, Redmond, Washington) just prior to being offered a date for surgery. Excel Macros were used to perform the randomisation (this was concealed from the allocator) and then lock the allocation with the patient's research information to address allocation bias. All patients' treatments in this study were delivered by the National Health Service and were free at the point of care. At the follow up visit, if the patient failed to attend, the patient was contacted and offered another appointment within one week. If they failed to attend this, they were considered lost to follow up from the study.

Outcomes reported in this study are detailed in the trial protocol (Version 2.0, 18/05/2016). Data collection for this study occurred at the pre-operative assessment,

the day of surgery, and the post-operative visit scheduled at 4 weeks after surgery (**Error! Reference source not found.**). Visual acuity and any investigations performed (corneal topography, specular microscopy etc.) were conducted by an optometrist or technician (DS, PH, DD) masked to the participant's treatment arm. Due to the nature of the intervention, neither the surgeon, surgical team nor the participant could be masked to their treatment arm. All clinical technicians and nurses were masked to the intervention received. Visual acuity (unaided, best corrected, and pinhole) was measured with a Snellen chart at 6 meters. Participants' refractive errors were collected using an RK-501A Autorefractor (Nidek Co. Ltd, Aichi, Japan). Biometry was performed using an IOL master 500 (Carl Zeiss Meditec AG, Switzerland). Corneal topography and central corneal thickness (CCT) were determined using Pentacam (Oculus, Germany). Macular Optical Coherence Tomography (OCT) was performed with Spectralis SD-OCT (Heidelberg Engineering, Germany). Endothelial cell count (ECC) was performed with Topcon SP-3000 Specular Microscope (Topcon Medical Systems, Oakland, NJ, USA). Visual comorbidities and risk factors for complications of cataract surgery were recorded prospectively. Risk of posterior capsular rupture (PCR) were calculated for patients using a composite risk calculation system[19]. PROMs were collected with the Cat-PROM5 tool and QoL were assessed using the EuroQOL EQ-5D questionnaire. The EQ-5D consists of 2 components: 5 questions about 5 dimensions of health-related quality of life (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) which are scored as 1, 2, or 3 (1 meaning no problems and 3 meaning extreme problems). The 5 responses are then weighted and combined to create a summary index with values 0-1, where 1 indicates no problems. The visual analogue scale is a continuous scale anchored by best imaginable and worst

imaginable health, with values ranging from 0 to 100 (where 100 indicates best possible health). EQ-5D was chosen as it is well recognized by public bodies (such as the National Institute for Health & Care Excellence) for comparative health economic analyses[20]. The Cat-PROM5 is a recently developed National Institute for Health Research (NIHR) funded questionnaire consisting of 5 questions which provide a Rasch calibrated psychometrically robust measure which is highly responsive to cataract surgery, in which a higher score indicates greater visual disability[17,18].

FLACS treatment was performed using the LenSx Femtosecond laser (Alcon Inc. Forth Worth, Tx, USA). Two surgeons (HWR, VKW) received training and full accreditation on the device in anticipation of this trial and performed at least 30 laser applications each before the trial began. The femtosecond laser was used to perform capsulotomy, lens fragmentation ± astigmatic keratotomies. Default laser parameters for all surgeons are detailed in supplementary material #1. Where the laser treatment could not be performed for whatever reason (e.g. repeated inability to dock, laser machine fault, etc.) patients underwent surgery in accordance with conventional CPS. Astigmatic keratotomies (FS-AKs) (within the FLACS group) or limbal relaxing incisions (LRIs) (within the CPS group) were offered to any patient with corneal astigmatism greater than 1 dioptre (D) based on corneal topography. The astigmatic results are presented elsewhere[21]. All cataract operations were performed under local anaesthetic. All operations were unilateral, and no other additional procedures were planned, other than arcuate keratotomies for the reduction of corneal astigmatism.

Following FL treatment, the patient was transferred to the operating theatre for the remainder of the cataract extraction. Phacoemulsification was performed using the

Infiniti phacoemulsification machine (Alcon Inc.) Patients undergoing CPS were prepared for surgery in the same way as those in the laser arm. Instead of receiving laser pre-treatment, they were brought straight to theatre. The default IOL used for in-the-bag placement was the Acrysof SA60AT (Alcon Inc). All operations were performed by surgeons who had completed at least 30 FLACS procedures (HWR, VKW, DOB).

Statistics

Baseline characteristics were summarised for each treatment arm (Table 3). Results were analysed primarily as per intention to treat. Evaluators were masked to the participants' treatment arm. For all evaluations of visual acuity as an outcome, patients with visually significant ocular co-morbidities were excluded prospectively. Snellen visual acuities were converted to LogMAR for analysis[22]. Continuous data was reported using means and standard deviations if data appear Gaussian. Binary data was reported as frequencies and percentages and evaluated with Fischer's exact test. Student's t-tests were used for parametric data. All statistical tests used a two-sided p value of α=0.05 unless otherwise specified. Intra-operative or post-operative complication were defined as any event that involved unintentional trauma to an ocular structure, requiring additional treatment, or having a negative effect on participants' eyesight. EQ-5D index scores were calculated using the visual analogue score method calibrated for the United Kingdom. Rasch calibrated Cat-PROM5 scores (logits) were calculated from the questionnaire responses in accordance with the developer's instructions [16].

Uncorrected distance visual acuity at 4 weeks was designated as the primary outcome with intra- and post-operative complications, refraction, corneal thickness, endothelial cell loss and quality of life outcomes and patient reported quality of vision pre-operatively and at 4 weeks after surgery selected as secondary outcomes. *A priori* calculations for sample size indicated a total sample size of 370 to have an 85% chance of detecting a 0.1 difference in LogMAR visual acuity and assumption of σ=0.32 with α=0.05 and a two-tailed analysis. This sample size was rounded up to 400 to account for the possibility of patients lost to follow up.

Results

427 patients were recruited to the study between August 2016 and June 2017. 27 patients withdrew from the trial before surgery. 400 eyes of 400 patients received surgery between November 2016 and June 2017 (200 CPS, 200 FLACS). 9 patients failed to attend their follow up appointments (2.3%). 7 participants lost to follow up were in the CPS group compared with 2 in the FLACS group (p=0.17). Only one of the participants lost to follow up had had an untoward clinical event (CPS arm), requiring referral to vitreo-retinal colleagues, and withdrew from providing further information to the study team, the remainder had had uneventful clinical courses (further clinical information on those lost to follow up – supplementary material#2). Although losses to follow-up were unequal between the arms the high overall rate of follow-up of 97.8% suggests that possible biases resulting from unequal follow-up are unlikely to be important.

182 (45.5%) of participants were male, 330 (82.5%) of operations were on first eyes, 216/400 (54%) were right eye operations. The average age of patients was 70.2 ± 10.4 years. Average pre-operative best corrected distance LogMAR visual acuity was 0.58 ± 0.47. Patient demographics and full baseline data can be seen in **Error! Reference source not found.**. Clinical and self-reported questionnaire measures were similar between the 2 groups. 155/400 operations (39.0%) were on-axis and 314/400 (78.5%) operations were performed with the main incision sited at the corneal limbus and 86/400 (21.5%) with clear corneal incisions. 49/400 (12.3%) of patients were excluded from post-operative visual acuity analysis due to pre-existing visually significant ocular comorbidities (FLACS n=28, CPS n=21). Cases were distributed

evenly between the three surgeons and between the two treatment arms (p=0.99) (Table 4).

FL treatment was delivered successfully to 96.5% of cases. Patients receiving FLACS spent, a mean time of 5.9±2.0 min in the laser room. 7 cases (3.5%) were unable to receive FL treatment and received CPS. The reasons were as follows: repeated bubbles in interface/flat cornea (n=1), administrative error (n=1), patient compliance (n=2), and patient's palpebral aperture too narrow (n=3). One of these patients suffered an intra-operative supra-choroidal haemorrhage; the others experienced uncomplicated operations. The average number of docking attempts was 1.3 ± 0.7 per patient. Reasons for failed attempts at docking and details of laser treatments delivered can be seen in supplementary material #1. Average duration of surgical time was 11.7min ± 3.5 for FLACS and 14.7 ± 6.8 for CPS.

Unaided VA (LogMAR) after CPS was 0.15±0.21 and 0.15±0.19 after FLACS (p=1), and pinhole corrected VA was 0.04±0.12 and 0.04±0.12 respectively (p=1) (Figures 1-4). Increase in CCT was 13μm±19 after CPS and 15μm±25 after FLACS(p=0.5). ECC loss was -9.7%±13.7 after CPS and -10.2%±13.7 after FLACS (p=0.76). Refractive mean spherical equivalent error was -0.14±0.60 diopters (D) after CPS and -0.12±0.60D for FLACS (p=0.74) (Figures 5-8). Change in CFT was 9μm±35 after CPS and 6μm±35 after FLACS (p=0.55)(Table 5). Cat-PROM5 demonstrated a substantial shift between pre- to postoperative completions, signalling a significant self-reported reduction in visual difficulty following surgery which was similar in the 2 intervention groups. The EQ5D summary index similarly reflected an improved score which was similar in the 2 groups. The EQ5D visual analogue score was however

unchanged in the FLACS group but increased in the CPS group (Table 5). There were no differences in total rates of intra-operative or post-operative complications (Table 6 and Table 7). There was a significant difference in the rate of PCR with a higher rate occurring in the CPS group (p=0.03).

Discussion

This is the largest RCT published to date comparing the safety and effectiveness of FLACS vs CPS including 400 eyes of 400 patients. All surgeries were performed by 3 surgeons at a single centre who had previously completed their FLACS learning curve having completed at least 30 cases. Patients were reviewed at 4 weeks post-operatively to perform clinical examination, assess for complications and gather post-operative data.

Overall, these results point overwhelmingly to an absence of clinical differences between FLACS and CPS (except for PCR and EQ-5D VAS), despite this study including a greater number of patients than any RCT preceding it. In many aspects, our findings are congruous with the available evidence and on occasion are in contrast with conventional understanding.

Previously reported gains in visual acuity for FLACS tended to be early (one week after surgery) or late (at 6 months) but not between 1 – 3 months[13,23]. In this current study we chose to evaluate patients at 4 weeks when the majority of post-operative oedema and inflammation has settled. At this time point, we found no difference in the post-operative visual acuity between the two groups (Figures 1 and 2, Table 5). We did not perform an immediate post-operative evaluation, although in accordance with our hospital protocol all patients were contacted by telephone to report and document any problems. It may be the case that FLACS has superiority in the early phase due to reduced ultrasound energy and reduced corneal oedema resulting in faster visual rehabilitation, followed by equivalence in the interim, with any late differences perhaps due to differences in late lens decentration or posterior capsular opacification[24-26]. It is

of note that we found no differences in CCT or ECL at one month after surgery, which might be expected if early corneal oedema delaying visual rehabilitation was a significant problem. We are also currently evaluating these patients at 12 months after surgery to determine late differences and these results will be reported later.

No differences were found in the IOP change between the two groups, As patients were reviewed at 4 weeks, post-operative IOP rises might have gone unnoticed. In the two patients seen with raised IOP post op, both were presumed due to a steroid response. Furthermore, no patients presented themselves to our service in the early post-operative phase with extremely high IOP.

This is the first large scale randomised controlled trial to evaluate rates of cystoid macular oedema (CMO) between FLACS and CPS. Our rates of cystoid macular oedema were equivalent between the two groups and there was no overall difference in the mean change in central foveal thickness. This is in keeping with previous reports[8,27]. Of the 7 cases of CMO in this study, risk factors were prospectively identified for 5 cases (previous macula off retinal detachment = 1, previous epiretinal membrane peel = 1, previous central retinal vein occlusion = 1, epiretinal membrane = 2).

Our study found a statistically significant increase in the rate of PCR in the CPS group. This is an important finding due to the associated risks of further complications in the post-operative phase associated with increased morbidity and cost [4,28]. The Cochrane review of published RCTs reported an overall rate of PCR in 0/529 (0.0%) cumulative FLACS cases compared with 1/547 (0.1%) for CPS[23]. We consider the rates of PCR

in both those groups to be lower than expected; perhaps reflecting patient selection for the studies, the expertise of the surgeons, or both. The EUREQUO case control study compared 2814 FLACS cases with 4987 CPS and found no significant difference in the PCR rates of 0.4% and 0.7% (p=0.79) respectively[29]. The two other largest studies of note included a case series of over 7000 operations in the public sector in the US (which found a greater rate of vitreous loss in the CPS group) [15] and a case-control study of over 4000 patients which found no significant difference in PCR rates[30]. Our study was performed in the public sector in a hospital based within an inner-city area of London with the accompanying demographics and high rates of co-morbidities. Of the patients sustaining PCR in our cohort the mean composite risk calculation score was 2.04% (Range 0.84% - 3.13%)[19], suggesting that although on the high side, the 3% rate in the CPS arm of our study was at least in part a reflection of the surgical case complexity in our patient cohort. As such, FLACS may carry more of an advantage in cohorts which have an existing higher rate of PCR (i.e. in tertiary units performing complex cataract surgery, surgeons in training, or in this case both) and conversely the benefits of FLACS may be more limited in simpler case-mixes. The benefits of FLACS for surgeons in training have been described previously[31].

All but one of the PCRs in the CPS group occurred during the phacoemulsification or segment removal stages. The lower rate of PCR in the FLACS group could imply that these stages of the operation are facilitated most by the FL. The nuclear segmentation patterns of the FL may produce more regular nuclear segments after cracking which may assist the surgeon by ensuring a more reproducible stage 2. This is certainly our anecdotal experience and is also reflected by the shorter surgical time in the FLACS group.

It is worth noting that the difference in PCR rates was only just statistically significant. One more PCR in the FLACS group or one less in the CPS group would have rendered this result not statistically significant (and the risk of type 2 error is increased when analysing outcomes with smaller numbers). However, It was possible to compare observed rates of PCR with expected rates as this study prospectively risk stratified patients according to a composite risk calculation system[19,28].

Self-reported visual difficulty and QoL outcomes were interesting. The Cat-PROM5 scores overall shifted significantly towards less visual difficulty with similar reductions in each group. The EQ5D scores likewise shifted towards better QoL postoperatively, with similar improvements in each group. There was a significant increase in the EQ-5D visual analogue score after CPS compared to FLACS (p=0.02), however in the absence of a plausible clinical explanation or safety issue, and as we found no differences in the EQ-5D-3L Index Score (p=1.0) or Cat-PROM5 Calibrated Score (p=0.49) we cannot suggest any reason why this result is not a type 1 statistical error. Furthermore the EQ5D visual analogue score is known to correlate poorly with the impact of cataract surgery[32].

Our anterior capsular tear rate was greater in the FLACS group (3% vs 1.5%) but this was not statistically significant. Anterior capsular tear rates in other RCTs were, again, exceptionally low. However Abell et al. found increased risk of anterior capsular tears in FLACS compared with CPS, reflecting the ‘postage-stamp edge’ microanatomy of the capsulotomy rim[9,10,26,30,33]. In our anecdotal experience the FL anterior capsulotomy is indeed more likely to tear than a manual continuous curvilinear

capsulorrhexis. This resulted in each surgeon adapting their surgical technique during each of our learning curves i.e. not to overly stretch the capsulotomy by removing large and dense fragments. This is in turn facilitated by predictable capsulotomy and lens fragmentation sizes created by the FL.

In contrast with other studies we did not find that FLACS resulted in more predictable refractive outcomes than CPS[1,7,26]. Our overall median absolute error (0.32D for FLACS and 0.29D for CPS) and proportions within ±0.5D, ±1.0D were similar between both groups and in keeping with other studies in the literature (Figures 5 and 6). However, in a subgroup analysis of this same study, we have shown better outcomes with FS-AKs compared with manual limbal relaxing incisions[21].

One more surprising result is that we did not realize the reduction in phacoemulsification energy (CDE) previously reported with FLACS (9.6 ± 7.0) compared with CPS (11.1 ± 9.8, p=0.08). There was a non-significant result, however perhaps our preference for segmentation of the cataract rather than fragmentation into cubes may have been a factor. 2 studies have demonstrated reduced ultrasound energy in FLACS, but either using a grid pattern, or segmentation with multiple concentric cylinders[34,35]. Shajari et al. recently published their findings that CDE was reduced in grid pattern compared with the segmentation pattern which was our favoured technique[36]. It follows therefore, that grid pattern softens the nucleus and permits more phacoaspiration, reducing CDE, in comparison with segmentation pattern which requires a nuclear disassembly technique resembling divide-and-conquer.

Previous studies have indicated that incorporating a femtosecond laser can have a negative impact on productivity, which can largely be attributed to transfer time between the laser and the surgical bed[37-39]. While we did not directly measure this transfer time, we have reported on the hub-and-spoke model we used for the femtosecond laser service and found that this resulted in marginal gains in productivity in the FL group[40].

The limitations of this study include that many clinical outcomes were evaluated leading to an increased risk of type 1 statistical errors. Furthermore, RCTs are often underpowered for safety and complications in cataract surgery are fortunately rare (making it harder to meaningfully evaluate). For example, one patient randomised to FLACS sustained a suprachoroidal haemorrhage (SCH). A case of SCH in FLACS has been reported in the literature, but it is currently unknown whether supra-physiological vacuum applied to the globe further increases the risk of this rare but potentially devastating complication[41]. The sample size required to test for such rare complications would be unfeasibly large. However, as this is the largest RCT published to date evaluating complication rates we believe this adds important information to the current literature, including being incorporated in future meta-analyses.

This large RCT compares the clinical outcomes of FLACS and CPS and confirms, in the majority, the non-significant differences between these two treatment modalities in terms of visual, refractive and a range of other clinical and patient reported outcomes, while suggesting a higher rate of posterior capsular tears following conventional phacoemulsification.

Acknowledgements

The authors would like to thank Tim Archer and Melody Ni for their help in reviewing the study protocol and Isabella Mullens and Justin Sung for their assistance in data collection.

Legends for figures and tables within the text

Figure 1. Unaided and corrected distance visual acuity at one month after FLACS

Figure 2. Unaided and corrected distance visual acuity at one month after CPS

Figure 3. Difference between unaided and corrected distance visual acuity at one month after FLACS

Figure 4. Unaided and corrected distance visual acuity at one month after CPS

Figure 5. Spherical equivalent refractive accuracy one month after FLACS

Figure 6. Spherical equivalent refractive accuracy one month after CPS

Figure 7. Postoperative refractive cylinder one month after FLACS

Figure 8. Spherical equivalent refractive accuracy one month after CPS

Table 1. Inclusion and exclusion criteria for enrolment into the study

Table 2. Schedule for data collection

Table 3. Baseline characteristics for the two treatment arms. (D= Dioptre, LogMAR = logarithm of minimum angle resolution, PCR = Posterior capsule rupture)

Table 4. Spread of operations between the three surgeons on the trial

Table 5. Post operative results for the two treatment arms .(D= Dioptre, LogMAR = logarithm of minimum angle resolution, PCR = Posterior capsule rupture)

Table 6. Intraoperative complications (*this patient had been randomised to FLACS but received CPS).

Table 7. Postoperative complications (*Both patients had been randomised to FLACS but one had received CPS).

Online Supplementary Material 1. (A). Reasons for failed individual attempts at docking with the patient interface of the femtosecond laser. (B). Complications relating to femtosecond laser delivery. (C). Details of laser procedures performed. N.B. 25.5% (n=51) of the conventional phacpemulsification surgery arm received manual limbal relaxing incisions. (D) Default laser settings for each surgeon. N.B. These were only the default settings and may have been changed as appropriate for any given case.

Online Supplementary Material 2. Patient Demographics for those lost to follow up.

What was known

- Meta analyses of several small randomised controlled trials (RCTs) showed little overall difference of visual and refractive outcomes between FLACS and CPS
- Little was known on whether a difference existed regarding patient reported outcome measures (PROMs) after FLACS or CPS

What this paper adds

- This is the largest RCT to date to demonstrate non-significance in clinical outcomes and PROMs between FLACS and CPS
- Furthermore there is reason to suggest that FLACS may reduce the risk of posterior capsular rupture.

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